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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,246	02/08/2000	Todd P. Foster	6231.N-CN1	2305

7590 07/15/2003

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 07/15/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/500,246

Applicant(s)

FOSTER ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 6/5/03
- 1) ☒ Responsive to communication(s) filed on 18 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>21</u> . | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Claim Objections***

Claim 36 objected to because of the following informalities:

It is uncertain whether Applicant is attempting to submit amendments under the old rule or new rule. Under the old rule, a clean copy and marked up copy was required with the clean copy being the official version for purposes of prosecution. Under the new rule a clean copy and marked-up copy are not required, instead all claims are to be presented, except for cancelled claims which may simply be identified as being cancelled, for example claim 2. (cancelled), with appropriate status indicators, with the currently amended claims being marked-up and new, previously amended or original claims being in clean form. Applicant herein has presented claim 36 alone as a marked-up copy and provided in an Appendix all claims as a clean copy. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis (U.S. Pat. 5,288,496) in view of Herbert et al. (U.S. Pat. 5,654,008) and Okada et al. (4,652,441) for the reasons of record set forth in the prior Office Actions and the further reasons below.

Lewis, Herbert et al. and Okada et al. were discussed in the prior Office Actions and the same are incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Also, there is amply motivation to combine or modify the references so as to effect both immediate treatment and treatment over a extended period of time (See Office Action (11/21/200), pg. 3).

Applicant argues that Lewis and Herbert et al. do not teach immediate release, however, Figure 1 of Lewis and Figure 11 of Herbert et al. clearly shows an immediate release of the steroid. Applicant argues that the claimed invention is different from the prior art composition in that the components are maintained as discrete, separate physical entities. However, the micro-particles are also discrete, separate physical entities. Applicant argues that the claimed composition allows for variability in the ration between growth promotor and other drug selected, however, the claims indicate that the drug is the same in each component. Also Lewis teaches that the microparticles can be mixed by size or by type so as provide for delivery of growth promoters in a muliphasic manner and/or in a manner which provides different growth promoters to the animal at different times, or a mixture of growth promoters to the animal at the same time (Lewis, Column 6, lines 43-55). Applicant argues that the polymer matrix when used in Applicant's invention is not biodegradeable. However, the claims clearly include a polymer matrix which is biodegradable.

Applicant argues that the methods for producing microcapsules and for obtaining sustained release of the drug in Okada et al. are very different than those of the instant

Application, however, Applicant does not appear to provide any explanation or evidence of this purported difference. Applicant also argues that Okada et al. does not disclose or contemplate addition of immediate release compositions to a prolonged release composition. However, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981). Applicant argues that Okada et al. does not teach or suggest all of the limitations in the Applicant's claims because it discloses different methods, however, as indicated above there is no requirement that Okada et al. teach or suggest all of the limitations of Applicant's claims. Finally, Applicant's claims use biodegradable polymers so Okada et al. does not teach away from Applicant's invention.

Claims 26-30, 33, 36-40, 43-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stevens et al. for the reasons of record set forth in the prior Office Actions and the further reasons below.

Stevens et al. was discussed in the prior Office Actions and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that Stevens does not disclose the immediate release and long-term release of the same drug. However, Stevens teaches an immediate release pellet and extended release pellet of antibiotics. As such, it would have been well within the skill of one of ordinary skill in the art would have been motivated to provide immediate release and long-term

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release of the same drug in that there would be provided an initial bolus of protection followed by a sustained protective effect.

Claims 26, 29-33, 36, 39-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rickey et al. for the reasons of record set forth in the prior Office Actions and the further reasons below.

Rickey et al. was discussed in the prior Office Actions and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that Rickey et al. teach away from the claimed invention, however, Rickey et al. teaches that the drug-loaded microparticles are dispensed to patients in a single administration, releasing the drug in a constant or pulsed manner and eliminating the need for repetitive injections (Column 17, lines 45-49). Applicant argues that Rickey et al. references does not teach or suggest all of the limitations in Applicant's claims because the methods for producing microcapsules and for obtaining sustained release of the drug are different from those of the claimed invention, however, Applicant does not appear to provide any explanation or evidence of this purported difference. Also, Rickey et al. teach that the microparticles can be mixed by size or by type so as provide for delivery of growth promoters in a multiphasic manner and/or in a manner which provides different growth promoters to the animal at different times, or a mixture of growth promoters to the animal at the same time (Column 17, lines 55-63). As such, Rickey et al. does suggest both immediate and long-term release of the same active agent.

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Examiner notes that the Guittard reference was not applied to reject any of the claims in the last Office Action. Further, the only combination rejection is the first-mentioned rejection above. The other rejections are based on a single prior art reference.

***Conclusion***

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

July 14, 2003



JOHN PAK  
PRIMARY EXAMINER  
GROUP 1000